UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,261	12/19/2000	Gary R. McLuen	NEI-00103	7751

7590 12/19/2003

Jonathan O. Owens
Haverstock & Owens LLP
162 North Wolfe Road
Sunnyvale, CA 94086

EXAMINER	
QUAN, ELIZABETH S	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/742,261	MCLUEN ET AL.
	Examiner	Art Unit
	Elizabeth Quan	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-26 and 35-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-26 and 35-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 December 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5 sheets* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second waste tube and the drain seal coupled to the waste tube for creating a seal between the first waste tube and one of the first and second drain must be shown or the feature(s) canceled from the claim(s). The drawings in corroboration with the specification do not show the drain seal in this specific configuration. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "520" has been used to designate mobile tube, waste tube, and holes. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "530" has been used to designate both gas fitting and waste tube system. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. It appears that are numerous errors in the specification regarding the drawings rendering comprehension of the invention difficult.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 24-26, 35-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The connection, interrelationship, and configuration of the structural elements and their function with respect to each other are not clearly described in the specification. Part of the clarity issue may be due to the use of the same reference characters for the same elements and the use of the different reference characters to describe the same elements.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 24-26, 35-42 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,844,306 to Hill.

Hill discloses a purging system, which may be used with a synthesizer (see figure). The system has a first bank (18) of vials and second bank (17) of vials each of which is associated with a first drain and second drain, respectively (see figure). Alternatively, since each bank of vials contains two banks of vials, each row of vials within the bank may be considered by itself a bank (see figure). Since each row of vials within a bank share the same drain line, the endpoints of each drain line proximal to the valve or the drain lines themselves may be considered the first and second drains (see figure). The system also has a pressurizing system for creating a pressure differential within a selective one of the first bank of vials and the second bank vials (see figure; col. 1, lines 26-32). The system is equipped with an air compressor (12) for pressurizing each bank of vials with different pressure (col. 1, lines 26-50). First (51) and second (55) waste tubes are in operative engagement with the first drain to purge material from the first bank of vials and the second drain to purge material from the second bank of vials. The waste tubes may be viewed as a continuous line from the tank to be filled to the drain (see figure). The system is capable of selectively and simultaneously purging the first bank of vials and second bank of vials by the manipulation of valves; however, this is more evident when each row of vials within a bank is viewed as a bank by itself. The connection or contact among the pipes would form a seal among these pipes. Since the term flexible is a relative term, the seal would have some degree of flexibility.

It is noted that "configured for use with a synthesizer containing a first bank of vials and a second bank of vials wherein the first bank of vials has a first drain and the second bank of vials has a second drain" is a statement of intended use, such that further mention of the elements in this intended use statement is not positively recited.

9. Claims 24, 35, 40 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,424,038 to Benz et al.

Benz et al. disclose a purging system (16) configured for use with a synthesizer, which has a first bank (15) of vials and second bank (14) of vials each of which is associated with first and second drains, denoted as either reference character (1) or (3) depending on the position of the slider (166) (figs. 1, 2, 4-7; col. 4, lines 10-26). A pressurizing system of pumps and valves creates a pressure differential within a selective one of the first bank of vials and second bank of vials. A first waste tube (167) engages the first drain to purge material from the first bank of vials and the second drain to purge material from the second bank of vials (col. 4, lines 10-26).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 31-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,472,672 to Brennan in view of WO 98/10857 to Zuckermann et al.

Brennan discloses a method of selectively and sequentially dispensing a plurality of reagent solutions to a plurality of vials divided into first and second banks of vials and selectively purging material for the first and second banks of vials using a polymer synthesis apparatus (20) (figs. 1-7).

The polymer synthesis apparatus comprises a delivery assembly (43) for controlling delivery of liquid reagents through an array of nozzles (22) mounted on mounting blocks (37) of head assembly (21) in nozzle rows (40) and columns (41), which align with selected vials (26) of plate (32) within sliding plate (33) of base assembly (25) via transport mechanism (27) (figs. 1-7; col. 5, line 60-col. 7, line 16; col. 8, lines 7-35). Each bank or row of nozzle is coupled to a different liquid reagent applied in a particular polymer synthesis (col. 6, lines 49-56). For instance, the first row of nozzles may only dispense the activator tetrazole while the second row

dispenses amidite thymidine (col. 6, lines 56-59). In oligonucleotide synthesis, this order of liquid reagent distribution may continue down the line for amidites adenosine, cytosine, and guanine, the auxiliary base AnyN, solvent wash/reaction solvent acetonitrile, Cap acetic anhydride, Cap N-methylimidazole, iokine, and deblockers dichloracetic acide or trichloracetic acid; all of which are reagents used for the synthesis of defined sequence oligonucleotides (col. 6, lines 59-66). The step of dispensing is performed in a parallel fashion since all wells within a row or bank are simultaneously addressed. The step of dispensing is performed in a serial fashion since each row or bank is separately addressed. The system permits simultaneous alignment of all the wells with all the nozzles (col. 6, lines 32-39).

Each vial contains a retaining device (84) positioned in the bottom of the vial between orifice (74) and solid support (75) for preventing the passage of the solid support through the orifice (figs. 5 and 6). The retaining device is preferably a polyethylene or glass fiber frit, which acts as a filter membrane permitting reagent solution to flow through while retaining the solid support and polymer chain grown thereon (col. 10, line 59-63).

After synthesis completion, reagent solution is purged from the vials through the orifice into drain (81) by increasing the gas pressure differential above the predetermined amount, which overcomes the capillary forces in the orifice (figs. 1, 3, 4-6; col. 10, lines 44-49). Subsequently, the purged reagent solutions may be drawn out of the drain through a waste tube (83), which may be coupled to a vacuum pump to create the pressure differential by forming a vacuum in the drain (figs. 1, 3, 4-6; col. 10, lines 50 and 51; col. 11, lines 55-57). Second and third waste tubes (82) are integrated with the gas flow assembly employed to flush the headspace in common chamber (31) of reagent toxins (col. 9, lines 34-66; col. 11, lines 3-6). The waste

tubes also control the pressure differential in the common chamber for purging the vials (col. 10, line 50-col. 11, line 28).

Note: The ambiguous term "engaging" may be interpreted as involving, operating, or using, such that a drain is engaged with a bank of vials with a waste tube when it is put in operation for purging the contents of the vials. The ambiguous term "disengaging" may be interpreted as not involving, not operating, or not using, such that the waste tube is disengaged from the drain when it is not purging the contents of the vials. Brennan discloses that purging occurs only after the completion of the synthesis reaction, such that the drain is engaged with a bank of vials with a waste tube when purging is in progress (i.e. the waste tube is withdrawing materials from the vials). During synthesis, purging is not in progress such that the waste tube is disengaged from the drain (i.e. waste tube is not active).

Brennan discloses engaging a drain with all banks of vials. Brennan fails to disclose engaging a drain with a certain bank of vials. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus of Brennan to engage a drain with a certain bank of vials since it is well suited for solid phase synthesis chemistry reactions such as polypeptides, peptoids, and polynucleotides in which a sequence of reaction steps are carried out in parallel using a plurality of reaction vessels as taught by Zuckermann et al. (abstract; figs. 2 and 4; page 3, lines 12-27; page 6, lines 16-19 and 26-28; col. 8, lines 7-9; col. 12, lines 13-15).

14. Alternatively, claims 25, 36, 37, 41, 42 are rejected under 35 U.S.C. 103(a) as obvious over (U.S. Patent No. 3,844,306 to Hill) or (U.S. Patent No. 5,472,672 to Brennan in view of WO 98/10857 to Zuckermann et al.) in view of U.S. Patent No. 2,684,255 to Abele et al.

In the event one would argue that Hill or Brennan in view of Zuckermann et al. do not disclose a flexible drain seal between the first waste tube and the selective one of the first drain and the second drain, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Hill or Brennan in view of Zuckermann to provide these flexible seals between the drains and tubes for connecting these sections in a manner of preventing leaks and minimizing stresses as taught by Abele et al. (col. 1, line 1-col. 2, line 4).

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. They include one or more limitations in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743

eq

Supervisory Patent Examiner
Group 1700